REMARKS

I. Status of Claims

Claims 1 to 22, 25-38, 44-45 and 58 were previously canceled from the application, without prejudice.

Claim 1 is amended by virtue of the present amendment. Support for amendment to specify that the particles of antidepressant have a mass median aerodynamic diameter of 10 μm or less is found in claim 46 of the application as filed. Support for the amendment to specify that 90% of the antidepressant has a particle size of 10 μm is found in claim 48 and on page 31, line 24 of the PCT application as filed.

By virtue of the present amendment, claim 48 is canceled, without prejudice, in view of the amendments to claim 23.

New claim 65 has been added. New claim 65 is identical to former claim 44 which was canceled in Applicant's September 4, 2009 Amendment.

It is respectfully submitted that no new matter was added in this amendment.

Obviousness

1. Rejection under 35 U.S.C. § 103(a) over Tam

In the current Office Action, claims 23-24, 39-43 and 59-64 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tam et al. (U.S. PreGrant Publication 2002/0161016).

Independent claim 23, as amended, recites:

> A method of treating premature ejaculation, the method comprising administering to a subject in need of such treatment a dry powder composition comprising an antidepressant by pulmonary inhalation, **wherein at least 90% of the antidepressant has a mass median aerodynamic diameter particle size of 10μm or less**.

As disclosed on page 16 of the PCT application, the present invention provides for a high performance pulmonary delivery of antidepressants for the reliable, convenient and efficient treatment of premature ejaculation. This high performance delivery enables rapid peak blood levels to be achieved and provide rapid clinical onset of the therapeutic effect, as demonstrated in the clinical trial evidence provided with the response to the last Office Action. Particles having a mass median aerodynamic diameter ("MMAD") of 10μm or less are advantageous because, as disclosed on page 17, lines 12-14 of the PCT application, particles having aerodynamic diameters of 10μm or more are likely to impact the walls of the throat and not reach the lungs.

The Tam reference is the only prior art document which discloses a medicament for premature ejaculation. It discloses a solution for treating premature ejaculation by pulmonary administration, said solution comprising clomipramine (col. 9, l. 16-24 and example 5). The Tam

reference neither discloses a dry powder for pulmonary inhalation or a medicament comprising an antidepressant wherein 90% of the antidepressant has a MMAD particle size of 10μm or less.

There is no teaching or suggestion provided by the Tam reference to use a dry powder as claimed for pulmonary inhalation.

Further, the Tam reference teaches a different formulation for pulmonary administration than that of the presently claimed invention, namely administration of a solution formulation for use in a pulmonary inhaler. As the Tam reference teaches the administration of a solution, not a dry powder, for pulmonary inhalation, the MMAD of a particle is not a relevant property to consider. For this additional reason, the Tam reference cannot teach or suggest use of a dry powder for pulmonary inhalation or a medicament comprising an antidepressant wherein 90% of the antidepressant has a MMAD particle size of 10μm or less.

Moreover, although the Tam reference does contemplate different delivery routes, it does not mention pulmonary delivery of dry powders. Rather, Tam contemplates the use of dry powders only for intranasal administration (col. 9, l. 48-50). Tam therefore teaches away from the administration of dry powders by pulmonary inhalation.

The claims are therefore inventive in light of Tam. In view of the foregoing, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) to claim 23 (and claims 24, 39-43 and 59-64 which depend from claim 23) as being unpatentable over Tam et al. (U.S. PreGrant Publication 2002/0161016) is respectfully requested.

2. Rejection under 35 U.S.C. § 103(a) over Tam in view of Staniforth

In the current Office Action, claims 46 to 54 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tam et al. (U.S. PreGrant Publication 2002/0161016) as applied to claim 23 above, and further in view of Staniforth et al. (U.S. PreGrant Publication 2003/0162835).

The Tam reference is discussed above with respect to independent claim 23 of the present invention. Claims 46 to 54 depend, either directly or indirectly from claim 23.

The Staniforth reference teaches composite excipient particles which are defined as particles of excipient material which have, upon their surfaces, an amount of additive material ([0014]). The composite excipient particles are suitable for use in a pharmaceutical composition comprising actives such as antidepressants (see Paragraphs [0008] and [0048]). Furthermore, 90% of the composite **excipient** particles in the Staniforth reference may have a diameter of less than 10μm (See Paragraph [0021]). However, the Staniforth reference does not disclose a dry powder wherein 90% of the antidepressant has a MMAD particle size of 10μm or less.

Further, the person skilled in the art would not consider combining the Tam reference with the Staniforth reference because the Tam reference teaches away from using dry powder for pulmonary inhalation. Even if the skilled person did combine the documents, he or she would not arrive at the claimed invention because the Staniforth reference fails to teach or suggest a dry power wherein 90% of the antidepressant has a MMAD of 10μm or less.

The claims are therefore inventive over the Tam reference in view of the Staniforth reference. In view of the foregoing, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) to claims 46 to 54 as being unpatentable over Tam et al. (U.S. PreGrant

Publication 2002/0161016), and further in view of Staniforth et al. (U.S. PreGrant Publication 2003/0162835) is respectfully requested.

3. Rejection under 35 U.S.C. § 103(a) over Tam in view of Lewis

In the current Office Action, claims 55 to 57 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Tam et al. (U.S. PreGrant Publication 2002/0161016), and further in view of Lewis et al. (U.S. PreGrant Publication 2002/0025299).

The Tam et al. reference is discussed above with respect to independent claim 23 of the present invention. Claims 55 to 57 depend, either directly or indirectly from claim 23.

The Lewis reference discloses an aerosol solution composition for use in an aerosol inhaler comprising an active material and a propellant containing a hydrofluoroalkane or a low volatility component to increase the MMAD of the aerosol particles. The Lewis reference fails to teach a dry powder formulation comprising an antidepressant, wherein 90% of the antidepressant has a mass median aerodynamic diameter particle size of 10μm or less as claimed in the present invention. The person skilled in the art would therefore not arrive at the claimed invention by combining the teachings of the Tam reference and the Lewis invention.

The amended claims are therefore inventive over the Tam reference in view of the Lewis reference.

Conclusion

This Response is being submitted in response to the Office Action dated December 31, 2009 in the above-identified application. Concurrently with this Response, Applicant submits a

petition for a three-month extension of time for filing a response, along with the requisite fee. Therefore the time for filing a response to the December 31, 2009 Office Action is thereby extended to May 31, 2010. Applicants note that May 31, 2009 was a federal holiday (Memorial Day), therefore the time for filing a response to the December 31, 2009 Office Action is thereby extended to June 1, 2010, and this Response is being timely filed. If it is determined that any fees are due in connection with this filing, the Commissioner is authorized to charge said fees to Deposit Account No. 50-0552.

An early and favorable action on the merits is earnestly requested.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: / Leslye B. Davidson/
Leslye B. Davidson, Reg. No. 38,854

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940